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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,246	12/01/2003	Kenneth Newman	03269/100M292-US3	1944

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,246	NEWMAN ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 16-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted January 18, 2006 is acknowledged.

1. The terminal disclaimer filed on January 18, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of application 10/925,783; 10/861,239 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 2-3, 7-11, 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Cooper et al. (IDS).

Cooper et al. treated postsurgical patients with a combination of 400 mg of ibuprofen and 5 mg of oxycodone for pain relieving. See the entire document. As to the pain relieving function recited in claims 22 and 23, note, such function would have been inherent to the method employed by Cooper et al. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating or preventing a malady or disease with old and well known compounds or

compositions. It is now well settled law that administering compounds inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use. Arguments that such therapeutic use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use.

3. Claims 2, 3, 5, 7-11, 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Dionne (IDS).

4. Dionne discloses a method of treating postsurgical pain by administering to the patient a dose of combination of 400 mg of ibuprofen and 2.5, 5, or 10 mg of oxycodone. For the combinations of 400mg/5mg and 400 mg/10mg (ibuprofen/oxycodone), partial pain relieve has been observed with 30 minutes. See, particularly, the abstract, and the figures at page 675.

Claim Rejections 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-11, 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (US 4,569,937, IDS), Cooper et al. (IDS) and Dionne (IDS).

7. Baker et al. teach the synergistic combination of oxycodone (a) and ibuprofen (b), wherein the ratio of a:b is from about 1:6 to 1:400 by weight, and the method of using the same for alleviating pain in mammal. The synergistic composition may be in the form of tablet and capsule. See, particularly, the abstract, the examples in columns 4-8, and the claims. Cooper et

al. and Dionne disclose specific single dose of the combinations herein claimed, i.e., 400mg/5mg and 400mg/10mg (ibuprofen/oxycodone), and the method of using the same for treating postsurgical pain. Partial pain relieve has been observed with 30 minutes for those combination. See, the entire document of Cooper et al. and the abstract, and the figures at page 675 in Dionne.

8. The cited references do not teach expressly a unitary dosage in the form of tablet or capsule comprising the combination 400mg/5mg or 400mg/10mg (ibuprofen/oxycodone), or the method of using such unitary dosage for pain relieving.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the particular unitary dosage herein and to use the same for treating acute pain.

A person of ordinary skill in the art would have been motivated to make the particular unitary dosage herein and to use the same for treating acute pain because the particular dosage amounts are known to be useful for treating pain and the combination dosage are known to be made into tablet and capsule. Pain due to surgical operation would be considered as acute pain. Further, since the method are known to be effective quickly after the administration of the dose, one of ordinary skill in the art would have been motivated to use the method for treating acute pain. Further, The optimization of a result effective parameter, e.g., effective amounts of a therapeutical agent, or its releasing profile in a dosage form, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Response to the Arguments

Applicant's amendments and remarks submitted January 18, 2006 have been fully considered, but are not persuasive.

With respect to the rejections under 35 U.S.C. 102, Applicants allege the cited references, Cooper et al. and Dionne use separated dosage forms. The examiner found no support for the allegation from the cited references. The references merely state the employment of combination of oxycodone and ibuprofen, nowhere in the references state, or require the two active agents need to be in separate dosage. In fact, Cooper et al. clearly state the studies "was a single dose, parallel group, factorial design clinical trial."

As to the 103 rejections, Applicants argue that one of ordinary skill in the art would have not been motivated to make and use a unitary dosage of oxycodone/ibuprofen because the side effect disclosed in the cited prior arts. Applicants further assert the cited references actually teach away from the claimed invention. The arguments are not persuasive. Note Cooper particularly teaches that the combination of oxycodone/ibuprofen (5mg/400mg) was statistically superior to ibuprofen See the abstract. Dionne particularly teaches that "additive analgesia can be achieved for the combination of a nonsteroidal anti-inflammatory drug and an orally effective opioid, with fast onset of relief for the combination of 400 mg ibuprofen and 10 mg oxycodone over the first 2 hours after administration, but at the expense of an increase incidence of adverse events." (see conclusion at page 673). As to the side effect, Dionne disclosed that adverse effects (mainly Drawsiness, nausea, vomited, and dizzy) were not significantly increased by the addition of 2.5 mg or 5 mg oxycodone. See particularly, pages 675-676. Further, Dionne provides guidance and direction as to use the combination. Dionne states "Given the need to provide greater analgesia to some patients after surgical procedure, the combination of an NSAID and an opioid appears to provide a therapeutic alternative if preventive strategies have not proved effective or were nor appropriate to the therapeutical environment" (page 677). Applicants are reminded that the

claimed amounts are within the range disclosed by Bake r et al. See dosage forms in columns 3-4. It is well settled that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955). As to the side effects, it is noted that "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore, it would have been obvious to one of ordinary skill in the art to make and use the combination of oxycodone/ibuprofen for treating acute pain as suggested by the prior arts.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617